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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,469	11/07/2001	Vadim Bichko	0342/1H395US1	7244

7590

01/28/2003

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EXAMINER

LI, BAO Q

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 01/28/2003

W

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,469

Applicant(s)

BICHKO, VADIM

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1-3 and 5, drawn to an isolated nucleic acid molecule encoding a replication competent recombinant hepatitis C virus (HCV), classified in class 424, subclass 228.1.

If group I is elected, Applicants are further required to select one of the nucleic acid molecule for the prosecution on the merits. This is not related to the species election because each of nucleic acid molecule has different structure and function, which has different patentable weight and constitutes a distinct invention. The nucleic acid molecule needs to be elected from: (1). Double stranded DNA, (2). A single stranded DNA, (3). A double stranded RNA, and (4). A single stranded RNA.

- II. Claims 6-11, drawn to an isolated nucleic acid molecule encoding a fragment of HCV, classified in class 536, subclass 23.72.

If group II is elected, Applicants are further requested to select one of sequence from SEQ ID NO 1-6 for the prosecution on the merits. This is not related to the species election because each of nucleic acid sequence has different structure and function, which has different patentable weight and constitutes a distinct invention.

- III. Claims 4 and 12-13, drawn to a cell line transfected with a nucleic acid molecule, classified in class 435, subclass 325.

Upon election of group III, Applicants are further required to elect one cell line for the prosecution on the merits. This is not the species election because each cell line has different characteristics that determines different susceptibility of carrying and producing HCV genome.

- i). Human hepatoma cell line Huh-7, ii). Human hepatoma cell line HepG2, iii). Hepatoma cell line PH5CH, iv). T. belanger liver cell line MBTL, v). human diploid fibroblast cell line VERO, vi). Secondary monkey kidney cell line CV-1, vii) T cell line MT-2, viii). T cell line HPMMa10-2, ix). T cell line MOLT-1 x). B cell line Daudi.

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xi). A cell line of HCVR2, xii) A cell line of HCVR8, xiii). HCVR9, ivx). A cell line of HCVR22 and xv). A cell line of HCVR24.

III. Claim 20, drawn to a method for screening an anti-HCV therapeutics, classified in class 435, subclass 3.

IV. Claims 21-22, drawn to a method for detecting antibodies against HCV, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I- III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally different products, e.g. the product of Group I is a nucleic acid molecule, whereas the product of the group III is a cell line.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to functionally different methods, e.g. the method of Group IV is used for screening an compound, whereas the method of the group V is used for detecting an antibody.

Inventions I and IV are related as process of using and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be practiced with materially different product or (2) that the product as claimed can be practiced by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process such as to produce antibody, whereas the process of the Group IV can be practiced with a HCV infected patient.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different searches and classifications. The restriction for examination purposes as indicated is proper.

1. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

4. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

5. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li
January 16, 2003


JAMES HOUSEL 1/27/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600